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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,345	04/16/2008	David Barshis	63365US008	4521

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	10/555,345	BARSHIS, DAVID	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/05, 06/09, 10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities: The specification is incomplete because it is missing the necessary period at the end.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **7-14** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a method of preventing nosocomial infections. However specification does not support the said claim because there is no showing in the specification or in the art that administration of a disinfectant such as chlorhexidine gluconate can **prevent** all nosocomial infections.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "*undue*". See ***In re Wands, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998).*** The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman, 230 USPQ 546*, the court recited eight factors

These factors include, but are not limited to:

1) The breadth of the claims,

2) The nature of the invention,

3) The state of the prior art,

4) The level of one of ordinary skill,

5) The level of predictability in the art,

6) The amount of direction provided by the inventor,

7) The existence of working examples

8) The quantity of experimentation needed to male or use the invention based on the content of the disclosure.

(1 and 2) *The breadth of the claims and the nature of the invention:* The claims are broad. The claims are drawn to a method of preventing nosocomial infections comprising applying a disinfectant such as chlorhexidine gluconate to a patient before inserting an endotracheal tube.

(3 and 5) *The state of the prior art and the level of predictability in the art:* The art teaches methods of reducing nosocomial infections comprising applying a disinfectant such as chlorhexidine gluconate to a patient in hospital. It is disclosed that such application can reduce the prevalence of nosocomial pneumonia in patients undergoing hear surgery (see Houston et al, DeRiso II, etc). Accordingly, the level of predictability of preventing the nosocomial infections with the said method, in the art is very low.

(6-7) The amount of direction provided by the inventors and the existence of working examples: Applicants have provided in the specification disclosure regarding reducing nosocomial infections by applying a disinfectant such as chlorhexidine gluconate. In fact reducing nosocomial infections is the only method disclosed in the specification. In view of the difficulty of preventing an infection, further testing would be necessary to use the invention as broadly as claimed.

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: The quantity of experimentation needed to make and use the invention based on the contents of the disclosure and the unpredictability asserted by the Applicant, is very high and not enabled by the specification.

Conclusion

For the forgoing reasons, the specification is not enabling for the scope of the claims.

Claims **1-3** are rejected under 35 U.S.C. 112, **first paragraph**, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims broadly recite a method of reducing nosocomial infections comprising applying a liquid disinfectant to the patients mucosa. The specification lacks disclosure on any disinfectant other than chlorhexidine gluconate. The specification provides insufficient written description to support the genus encompassed by the claim (any disinfectant).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed disinfectant, chlorhexidine gluconate, the skilled artisan cannot envision the broad scope of disinfectant encompassed, regardless of the knowledge of the disinfectants in the art. Adequate written description requires more than a mere disclosure of a genus.

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above disclosed species of chlorhexidine gluconate, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus

because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision.

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim **6** provides for the use of chlorhexidine gluconate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hawtin (GB 2338649).

Hawtin teach a nasal spray of chlorhexidine to nasal mucosa for the management of infections. The aerosol composition comprises an antiseptic an emulsion and a propellant. The antiseptic is preferably triclosan or **chlorhexidine gluconate** (see abstract).

Hawtin disclose that an example of a suitable formulation would be the antiseptic triclosan or chlorhexidine dissolved in an oil-in-water emulsion. This emulsion is then filled into suitable aerosol container, sealed with suitable metering aerosol valve, followed by the injection of a suitable propellant (see page 5, lines 21-25).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Grap et al (Duration of action of a single, early oral application of chlorhexidine on oral microbial flora in mechanically ventilated patients, XP- 002506103).

Grap et al teach that pneumonia is a common complication of mechanical ventilation and responsible for 90% of nosocomial infections in this population. Pneumonia is also the second most common nosocomial infection in the United States.

Colonization of the oropharynx is one of the most critical risk factors for the development of nosocomial pneumonia in intubated patients (see introduction).

Grap et al disclose that after intubation, the endotrachial tube provides a pathway for direct entry of bacteria from the oropharynx through an open glottis to the lower respiratory tract (see page 84, col. 1, lines 18-23).

Grap et al disclose that use of a single application of CHG (2 ml of 0.12% as **spray and swab**) was tested in a study. The results suggest that use of CHG in the early post-intubation period may mitigate or delay the development of VAP. Specifically, a decline in the level of oral bacterial growth was found only in the treatment groups (see Discussion on page 88).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al (6,290,984) in view of Raad et al (US 20030078242).

Tapolsky et al teach a non water-soluble pharmaceutical carrier gel which adheres to mucosal surfaces, providing protection to the treatment site and delivery of pharmaceuticals to the site of application, surrounding body tissues and bodily fluids (see abstarct and summary).

The pharmaceutical component may be a bactericide or disinfectant such as **chlorhexidine** (see col. 6, lines 18-20). The solutions and gels may be prepared by various methods known in the art. The gel may be applied to the treatment site by **spraying**, dipping, or direct application by finger or **swab** (See col. 7, lines 32-55).

Tapolsky et al lacks specific disclosure on reducing nosocomial infections. However this deficiency is cured by Raad et al.

Raad et al teach that most **nosocomial infections** are caused by the contamination of medical devices. The endotracheal tube is considered a common vehicle for colonization/contamination leading to nosocomial pneumonia (see [0005] and [0006]). Raad et al teach a method of coating a medical device with an antiseptic composition (see [0023]). One suitable antiseptic agent include **chlorhexidine** (see [0016]). The antiseptic composition can coat or impregnate a surface (see [0021]). Suitable surfaces may be skin or **mucosal surfaces** (see [0028]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tapolsky et al on applying biocide compositions to mucosal surfaces with the teachings of Raad et al on applying antiseptic (biocide) compositions to mucosal surfaces and medical devices for reducing nosocomial infections with a reasonable expectation of successfully preparing a biocidal composition applied on the mucosal surfaces of a patient by a spray or swab to manage infections, bacterial growth and to reduce nosocomial infections. Both references teach chlorhexidine as a suitable biocide. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al (6,290,984) in view of Raad et al (US 20030078242) and in further view of Seifert (5,035,348).

Tapolsky et al and Raad et al, discussed above lack specific disclosure on a swab that has a hollow handle and a frangible tip. However theis deficiency is cured by Seifert.

Seifert disclose an engineered swab-type article intended for delivery of liquid products to the skin. Therein is disclosed a flexible stick-like fluid dispenser mounted with a cotton tip. A frangible seal separates the fluid compartment from the tip. Upon application of force against the seal, a separation wall breaks allowing fluid to permeate the cotton tip.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have implemented the specifics of Seifert's swab with the method of reducing nosocomial infections of the combined references because complete sterility is very important in reducing contamination during treatment and a self contained sealed chlohexidine swab would have been ideal for such treatment. In other words, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Claims 1, 3-9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (Effectiveness of 0.12% chlorhexidine gluconate oral rinse in reducing prevalence of nosocomial pneumonia in patients undergoing heart surgery, AJCC) in view of Zygmont (5,846,215).

Houston et al perform a study with the objective that decreasing the levels of bacteria in the oropharynx should reduce the prevalence of nosocomial pneumonia and to test the effectiveness of 0.12% chlorhexidine gluconate oral rinse in reducing prevalence of nosocomial pneumonia in patients undergoing heart surgery. Houston et al conclude that although rates of nosocomial pneumonia were lower patients treated with Peridex™ (chlorhexidine gluconate) than in patients treated with Listerine, the difference was significant only in those patients intubated more than 24 hours who had the highest degree of bacterial colonization (see page 567 and 569).

Houston et al lack specific disclosure on application being made by a swab. However this deficiency is cured by Zygmont.

Zygmont teach a **swab** including an elongated stem and an absorbent covering such as cotton surrounding opposite tips of the stem. An antimicrobial agent is dispersed within the absorbent covering (see abstract). One suitable antibacterial agent is chlorhexidines (see col. 55-62). One preferred agent is chlorhexidine digluconate (see col. 4, lines 14-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Houston et al on a method of reducing nosocomial infections by applying a chlorhexidine gluconate formulation to their oral mucosa with the teachings of Zygmont on applying antiseptics such as chlorhexidine compositions to mucosal surfaces by way of a swab for reducing

nosocomial infections with a reasonable expectation of successfully preparing and applying an antiseptic agent such as chlorhexidine gluconate applied on the mucosal surfaces of a patient by a swab to manage infections, bacterial growth and to reduce nosocomial infections. Both references teach chlorhexidine as a suitable antiseptic agent. One of ordinary skill in the art would have been motivated to have implemented the swab of Zygmont for the application of chlorhexidine gluconate because many patients in hospitals are not able to do so by way of an oral rinse and as such a nurse would have to assist them. A swab would have been a logical application method. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

While the references do not specifically disclose a swab with a scored frangible tip, it would have been obvious to one of ordinary skill in the art to have modified the swab of Zygmont so that there is sealed amount of antiseptic agent within the swab which reduces possibility of contamination. As such the said modifications would have been within the capabilities of one of ordinary skill in the art and would have been a necessary design choice.

Claims 1-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616